

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA

Plaintiff,

v.

Civil Action No.: 22-CV-1159

B4B EARTH TEA LLC, a limited liability
company;

B4B CORP., a corporation; and

ANDREW MARTIN SINCLAIR, individually
and as an officer of B4B EARTH TEA LLC and
B4B CORP.,

Defendants.

SUPPLEMENT TO EXPERT REPORT OF DR. MARITON DANIEL DOS SANTOS

Following the submission of my Expert Report in this case, I reviewed the May 30, 2024 deposition of Defendant Andrew Martin Sinclair at the U.S. District Courthouse in Brooklyn, New York and all of the deposition exhibits. My review of these materials did not change any of my opinions in this case, but it did strengthen several of my opinions.

Mr. Sinclair's deposition testimony supports and confirms several of the opinions I expressed in my Expert Report:

That, based primarily on Mr. Sinclair's website and social media posts and text and app conversations with potential customers, which he confirmed that he made, B4B Earth Tea is a drug pursuant to 21 U.S.C § 321(g)(1). Tr. 80:8-11; Tr. 81:19-83:7; 85:21-87:10; 87:18-90:16; 91:5-19; 92:4-16; 93:4-19; 96:22-99:4; 99:6-104:5; 106:23-109:5; 109:21-110:21; 111:9-25; 112:3-113:24; 114:3-115:24; 116:2-117:17; 118:7-19; 118:23-122:3; 123:24-127:6; 128:4-20; 129:14-133:6; 135:15-136:7; 138:7-139:23; 140:3-144:10; 144:12-145:14; 145:18-149:11; 149:17-153:19; 153:21-155:21; 155:25-156:15; 157:18-22; 158:18-159:11; 159:17-160:4; 161:5-163:9; 171:24-172:24; 173:2-177:19; 178:17-180:12; 186:10-21; 188:13-189:22;

That B4B Earth Tea is not generally regarded by scientific experts as safe and effective against COVID-19 or any other disease. Tr. 324:7-13; 324:16-19;

That neither Mr. Sinclair nor anyone else ever submitted a New Drug Application, Abbreviated New Drug Application, or an Investigational New Drug Application to FDA for B4B Earth Tea. Tr. 321:24-322:25; and

That neither Mr. Sinclair nor anyone else has ever received any approvals from FDA for B4B Earth Tea. Tr. 323:9.

Mr. Sinclair testified that he has no formal medical or scientific education or work experience. Tr.15:12-16:18; 17:10-24; 18:6-20; 20:8-22; 21:8-12. Mr. Sinclair either does not know or misunderstands many basic scientific terms and concepts. Tr. Tr. 24:23-25; 26:21-27:2; 27:23-25; 28:19-30:14; 35:8-22; 263:17-19; 263:23-264:5; 267:20-268:2; 269:12-25; 270:2-23; 273:15-274:3. He also has no familiarity with the statutes and FDA regulations that apply to the disease-specific statements of efficacy he has made, Tr. 22:12-21; 24:20-24, many of which statements I cited in my Expert Report.

In addition, the evidence relating to his "independent research" relating to COVID-19 and other diseases consists of rough, incomplete and largely unsubstantiated notes based primarily on phone calls, texts and videos with people who have tried B4B Earth Tea; internet searches; and Mr. Sinclair's own personal experience with COVID-19. Tr. 214:5-217:23; 228:3-232:25; 244:9-254:22. As is the case with the clinical trial of B4B Earth Tea in India, Mr. Sinclair's "independent research," is insufficient to establish the efficacy and safety of the B4B Earth Tea products with regard to COVID-19 or any other disease. This "independent research" does not satisfy the statutory requirements to establish that a product is generally recognized as safe and effective.

I reserve the right to further supplement my Expert Report, this supplement thereto, and my testimony.

Dated: September 6, 2024.



Mariton Daniel dos Santos, *Ph.D., Pharm.D.*
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
The Office of Dietary Supplement Programs (ODSP)
Division of Policy and Regulations Implementation (DPRI)
Regulations Implementation Branch (RIB)